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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/302,239 04/29/99 NELSESTUEN

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EXAMINER

HM12/0913

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ART UNIT

PAPER NUMBER

1653

DATE MAILED:

09/13/01

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/302,239

Applicant(s)

Nelsestuen

Examiner

F. MOEZIE

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 21, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-20 is/are pending in the application.
- 4a) Of the above, claim(s) 15 and 18-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-14, 16, and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1 and 3-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

STATUS OF CLAIMS

Claims 1, 3-14, 16 and 17 are pending examination in this Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

COMPLIANCE WITH THE SEQUENCE LISTING REQUIREMENTS

Compliance with the Sequence Listing Requirements is incomplete. This application fails to comply with the requirements of 37 CFR 1.821 through 1.825. To comply with the Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Note: Upon compliance with the requirements applicant must also amend the application to provide SEQ ID NOS in the SPECIFICATION (at lest in the first occurance), in All EXAMPLES and THE CLAIMS.

REJECTION - 35 U.S.C. 112, FIRST AND SECOND PARAGRAPHS

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The rejection of claims 1, 2-14, 16 and 17 under **35 U.S.C. 112, first paragraph**, regarding the lack of possession for the claims is maintained for the reasons of record, paper no. 12, mailed 3/16/01 and the reasons infra.

The rejection of claims 1, 3-14, 16 and 17 under **35 U.S.C. 112, first paragraph**, regarding the lack of enablement for the claims is maintained for the reasons of record, paper no. 12, mailed 3/16/01 and the reasons below.

The rejection of claims 1, 2-14, 15 and 16 under **35 U.S.C. 112, second paragraph**, regarding the indefiniteness of the claims is maintained for the reasons of record, paper no. 12 and the comments below.

REJECTION - 35 U.S.C. 103 (a)

The rejection of claims 1, 3-14, 16 and 17 under **35 U.S.C. 103 (a)** over Watanabe et al in US 5,516,640 is withdrawn for the reasons cited below.

RESPONSE

Applicant's arguments and remarks filed June 21, 2001, paper no. 13 have been fully considered and found persuasive in-part.

The earlier **objection to the claims** regarding the inclusion of the non-elected subject matter into the elected claims is withdrawn in view of the amendment and cancellation of the non-elected subject matter from the claims.

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Remarks regarding the **Sequence Listing Requirements** that “As indicated previously, sequence identifiers are present throughout the specification and are not necessary in the drawings or in the claims” page 2, paragraph 5, are not well taken. See, the Note above for full compliance, wherein **Applicant must** also amend the specification --- and **THE CLAIMS**”.

Remarks regarding the variations in the amino acid numbering for Factor VII has been considered, because a specific position is cited in the claims - it follows that there is a specific sequence of amino acid (sequence identifier) to which it/they refer(s). Such a sequence identifier must be in the claims for the numbers to have any significance and the claims could properly be searched. Applicants’ remarks that “when a claim recites a particular position such as amino acid 11 for factor VII, it is actually position 10 of factor VII in the sequence listing” (page 2, last paragraph of remarks) have been considered. The claims are drawn to a Factor VII or VIIa polypeptide and as such their **actual** positions **must be** represented in the claims by means of its/their sequence identifier.

Remarks regarding the rejection of the claims under **35 U.S.C. 112, first paragraph**, regarding the possession of the claimed subject matter at the time of filing has been considered, but not found persuasive. Applicant alleges that “It would be **apparent** to a person of ordinary skill in the art that **polypeptide fragments could be produced**” (remarks, page 5, first paragraph). Clearly, this statement is not indicative of the applicants’ possession of the claimed subject matter at the time of filing, especially in view of the lack of any reference(s) showing what is/was apparent to a person of skill in the art at the time of filing of this application.

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Since no fragment(s) were produced by the applicant, claims drawn to a fragment of the polypeptide used in determining membrane affinity (pages 24-25 of the specification) of factor VII polypeptide carries little or no weight regarding the possession of the fragments of the polypeptide. In fact, reference made to Fig. 1 wherein the protein itself is used in the assays- and not a single fragment.

Remarks regarding the rejection of the claims under **35 U.S.C. 112, first paragraph**, regarding the enablement for the claimed subject matter have been considered, but not found persuasive. Applicants Remarks that GLA domain contains 9-13 - carboxy amino acid residues in the N-terminal region of the polypeptide "**typically from amino acid 1 to amino acid 45**" has been considered, however the claims call for a substitution at exact residues 11, 29 and/or 33. Note, Typically is not indicative of a specific amino acid being substituted at a specific site in a known sequence of polypeptide - as claimed. Therefore, enablement is lacking for the claims.

Remarks regarding the rejection of the claims under **35 U.S.C. 112, second paragraph**, is maintained because the claims are indefinite and confusing as to which amino acid is being replaced (original amino acid being replaced) and the sequence of the amino acids claimed (sequence identifier) which shows the exact position of the substitution in the sequence. Also, the sequence identifier is required for a proper search.

The rejection of the claims under **35 U.S.C. 103 (a)** over US 5,516,640 is withdrawn at this time because further prior art search is required to verify the patentability of what is being claimed verses the prior art teachings.

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Applicants' remarks regarding references AG and AH cited in **Form PTO-1449** have been noted. The references not initialed are/were not among the references present in the file. Applicant may file a copy of these references for consideration by PTO.

Any inquiry concerning this communication should be directed to F.T. Moezie at telephone number (703) 305-4508 or Dr. LOW (SPE) at 308-2923.

J. J. Moezie
MOEZIE
PRIMARY EXAMINER
ART UNIT 1653